K071885

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

Philips series of Multi-Patient Cuffs and Single-Patient Cuffs

Submitter's Name and Address

Submitter's Name:	Philips Medical Systems
Division:	Medical Consumables and Sensors
Address:	3000 Minuteman Road
City, State, and Zip:	Andover, MA, 01810

DEC 2 0 2007

Contact Person

Name:	Peter Schipelliti
Title:	Regulatory Affairs Specialist
Telephone:	(978) 687-1501
Facsimile:	(978) 659-7712
E-mail:	Peter.schipelliti@philips.com

Date of Summary

Date:	December 11, 2007

Manufacturing Facility Address

Manufacturer:	Philips Medical Systems
Address:	3000 Minuteman Road
City, State, and ZIP:	Andover, MA, 01810

Establishment Registration Number

Est. Registration Number:	1218950

New Device Details

Proprietary of Trade Names

Proprietary or Trade Name:	Philips series of Multi-Patient Cuffs and Single-Patient Cuffs

New Device Common Name

Common Name:	Blood Pressure Cuff

New Device Class

Device Class:	Class II

New Device Product Code

Device Procode:	DXQ

New Device CFR

Device CFR:	870.1120

New Device Classification Panel

Classification Panel:	Cardiovascular

New Device Classification Name

Classification Name:	Cuff, Blood Pressure

Reason for submission

Reason for submission	Modified Devices

Predicates

Predicate #1	(K001333)	Reusable Non-invasive Blood Pressure Comfort Cuff
Predicate #2	(K901252)	Disposable Non-invasive Blood Pressure Cuff
Predicate #3	(K884421)	Reusable Non-invasive Blood Pressure Cuff

Comparison of Technological Characteristics

The modified devices have the same technological characteristics as the legally marketed predicate devices. Safety characteristics are unchanged by these modifications

Summary of Intended Uses

Philips Multi-Patient and Single-Patient cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, pediatric and adult human blood pressure.

Description of Device

The device comprises tubing attached to an inelastic sleeve with an integral inflatable bladder that is wrapped around a patient's limb. It is secured by a hook and loop fastener. Device tubing is attached to an NIBP measuring system.

Device Testing

Device testing was performed according to the Validation Traceability Matrix. These activities were conducted to establish the performance and reliability characteristics of the modified devices. All tests passed.

Voluntary Standards Used in Determination of Substantial Equivalence:

The cuffs were tested according to:

- ANSI/AAMI SP10:2002 +A1:2003 "Manual, electronic, or automated sphygmomanometers"
- EN 1060-1:1995 +A1:2002; "Non-invasive sphygmomanometers Part 1: General Requirements"
- EN 1060-3:1997 +A1:2005; "Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems"
- IEC 60601-1:1988 +A1:1991 +A2:1995; "Medical Electrical Equipment – Part 1: General Requirements for Safety"
- IEC 60601-2-30:1999; "Medical electrical equipment Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment"
- ISO 10993-1:2003; "Biological evaluation of medical devices – Part 1: Evaluation and Testing"

All tests passed and therefore it is concluded that the product is safe and effective.

Conclusion

Based on similarity in technology, characteristics and the same intended use as the predicates, these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Philips Medical Systems
c/o Mr. Peter Schipelliti
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810-1099

Re: K071885
Trade/Device Name: Multi-Patient Cuffs, Models M4552B, M4553B, M4554B, M4555B, M4556B, M4557B, M4558B, M4559B, M4562B, M4563B, M4564B, M4565B, M4566B, M4567B, M4568B, and M4569B (16 Models); and Single-Patient Cuffs, Models M4572B, M4573B, M4573B, M4574B, M4575B, M4576B, M4577B, M4578B, M4579B, M4582B, M4583B, M4584B, M4585B, M4586B, M4587B, M4588B, and, M4589B (16 Models)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: OED
Dated: November 21, 2007
Received: November 23, 2007

Dear Mr. Schipelliti:

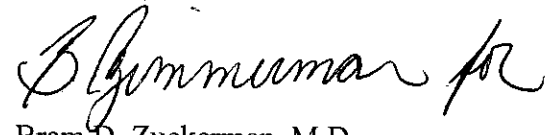
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PHILIPS

510(k) Number K071885

Device Name: **Philips series of Multi-Patient Cuffs and Single-Patient Cuffs**

Indications For Use:

Philips Multi-Patient and Single-Patient cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, pediatric and adult human blood pressure.

Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071885